

REMARKS

Claims 1-26 and 31-38 remain in this application. Claims 1, 6, 18, 20, and 36 have been amended, and claims 39-55 have been added. Independent Claims 41, 48 and 55 are generic to two or more species. Claims 6, 18, and 36 were amended solely to correct obvious typographical errors. Regarding claims 1 and 20, support for the amendments can be found, for example, at lines 3-22 of page 31 of the specification. No new matter is believed to be added by way of this amendment.

Comment on the Response to Arguments:

Regarding the Wallace et al. reference, Wallace et al. discloses an occlusion device and is devoid of any suggestion that the occlusion device is capable to serve as a tissue connector assembly. The Wallace et al. occlusion device has one or more vaso-occlusive members that are connected by electrolytically disintegratable links. Referring to the embodiment of FIG. 1, electrolytically disintegratable link 106 is shown between vaso-occlusive members 102 and 104, which are shown in the form of coils. The coils may be formed so that they are essentially linear as they pass through a delivery catheter and then assume a randomly oriented relaxed condition after they are released from the catheter (col. 5, lines 49-54).

In the Office Action, it was advanced that Wallace's vaso-occlusive member is capable of connecting two tissues based on a hypothetical illustration provided in the Office Action and designated Figure 1. First, Applicant respectfully points out that said Figure 1 is the Examiner's hypothetical drawing and is not present in the Wallace et al. patent and therefore should not form a basis for a rejection under 35 U.S.C. 102.

Further, it is not clear how the catheter in Wallace et al. can get stuck in the openings of two aneurysms as hypothetically set forth in the Office Action. For example, the distal end of the Wallace et al. catheter only appears to be capable of entering one aneurysm opening after which the occlusive device is deployed, the disintegratable link electrolytically disintegrated, and the catheter withdrawn. It does not appear possible to have the catheter simultaneously extend into two aneurysm openings as shown in the Office Action hypothetical. That is, although the drawing shows the catheter distal end extending into one aneurysm opening and the catheter proximal end extending into the opening of the other aneurysm, this deployment does not appear

possible. Even if it were, Wallace et al. certainly could not have intended that the catheter be left behind and permanently implanted in the patient. Also Wallace et al. certainly did not intend that the catheter and occlusive device be positioned as shown in the Examiner's hypothetical drawing where they obstruct the vessel lumen and could create serious complications.

Applicants also note that the hypothetical drawing in the Office Action does not account for how the disintegratable link, which was electrically connected to power supply 518, was positioned prior to electrolytic disintegration thereof to release the occlusive members. This further raises doubt as to the possibility of the catheter and occlusive device being positioned as shown in the Examiner's hypothetical.

The argument regarding Chervitz et al. also is improper. In the "Response to Arguments," it was advanced that that it would have been obvious to incorporate Wallace et al.'s occlusive members into Chervitz et al. It also was asserted that the Wallace et al. clips 102 and 104 met the mechanical features of the instant application's clips 1703' and 1703''. Applicant disagrees. A simple reading of Applicants' specification clearly shows that Wallace's occlusive coils 102 and 103 do not mechanically correspond to Applicants' clips. Further, the Office Action "Response to Arguments" provides no reason why one would incorporate occlusive coils into Chervitz et al. It appears that the Examiner is relying on impermissible hindsight application of the teachings of Applicants' invention. Further discussion is provided below with respect to Applicants' claims.

Section 102:

Claims 1-14, 20-23, and 31-35 were rejected under 35 U.S.C. §102(b) as being anticipated by Wallace et al. (U.S. Patent No. 5,941,888). Reconsideration and withdrawal of this rejection is requested.

Independent Claim 1:

Claim 1 as amended recites:

A tissue connector assembly comprising a surgical fastener comprising two clips, each sized and shaped to attach tissues and hold the tissues together therein, and a bridge portion connecting said two clips and spacing said clips from one another.

In contrast to the claimed tissue connector assembly, Wallace et al. discloses an occlusion device. The Wallace et al. occlusion device has one or more vaso-occlusive members that are connected by electrolytically disintegratable links. Referring to the embodiment of FIG. 1, electrolytically disintegratable link 106 is shown between vaso-occlusive members 102 and 104, which are shown in the form of coils.

The Wallace et al. coils 104 and 106, which have been advanced in the Office Action as corresponding to the Applicant's claimed clips, are not described as being sized and shaped to attach and hold tissues together therein as set forth in Applicant's amended claim 1. This is consistent with the disclosure, which describes them as occlusive members, not clips. Therefore, Wallace et al. does not anticipate claim 1.

Independent Claim 20:

Claim 20 as amended recites:

A tissue connector assembly comprising:
a surgical fastener comprising two clips sized and shaped to attach tissues and hold the tissues therein including at least one self-closing clip having an open configuration and a closed configuration, where said open configuration is a biased configuration and said closed configuration is an unbiased configuration, and a bridge portion having a substantially straight portion connecting said two clips; and

a release mechanism having a first position to bias said self-closing clip in said open configuration, and a second position to unbias said self-closing clip into said closed configuration.

The foregoing arguments made regarding claim 1 apply with equal force to claim 24. Wallace et al. does not disclose two clips sized and shaped to attach tissues and hold the tissues therein. Therefore, Wallace et al. does not anticipate claim 20.

Independent Claim 31:

Claim 31 recites:

Surgical clip apparatus sized and shaped to attach tissues comprising an elongated member, a pair of coils surrounding at least a portion of said elongated member, said pair of coils being serially arranged and spaced from one another along said elongated member, said elongated

member being shape memory material and having an unbiased shape, which includes a plurality of loops, and a biased shape, said elongated member tending to move toward said unbiased shape from said biased shape.

In the rejection, it was advanced that Wallace et al.'s coils 102 and 104, each surround a portion of an elongated member, which according to Figure 1 corresponds to electrolytically disintegratable link 106. In other embodiments, electrolytically disintegratable links correspond to elements 224, 526, and 612. These links are not shown, described, or suggested as having an unbiased configuration, which includes a plurality of loops. Nor are the links described as tending to move toward such an unbiased shape from a biased state. Therefore, Wallace et al. does not anticipate claim 31.

The remaining claims, which depend from independent claims 1, 20, and 31, are allowable for reasons provided above as well as for containing subject matter not disclosed or suggested in the cited references. For example, Wallace et al. does not disclose or suggest surrounding a substantial length of a self-closing clip with a coil as described in claims 7, 12, and 21, a release mechanism with first or first and second positions as described in claims 10 and 11, or the enlarged portions described in claim 35.

Section 103:

Claims 15-19, 24-26, and 36-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Chervitz et al. (U.S. patent No. 5,645,568) in view of Wallace et al. Applicant requests reconsideration and withdrawal of this rejection.

The foregoing rejected claims include two independent claims, independent claims 24 and 36, which are reproduced below for reference.

Claim 24 provides:

A tissue connector assembly comprising:

a surgical fastener having two ends including a first end and a second end and including two clips sized and shaped to attach tissues including at least one self-closing clip, and a substantially straight bridge portion connecting said two clips; and

two tissue piercing members including a first tissue piercing member releasably coupled to the first end and a second tissue piercing member releasably coupled to said second end.

Claim 36 provides:

Tissue connector apparatus comprising a surgical clip sized and shaped to attach tissues, first and second tissue piercing members each having first and second end portions, first and second couplings, and first and second flexible members, said surgical clip having first and second end portions, said first coupling being coupled to said first end portion of said surgical clip and said second coupling being coupled to said second end portion of said surgical clip, said first flexible member having a first end portion coupled to said first coupling and a second end portion secured to said second end portion of said first tissue piercing member, said second flexible member having a first end portion coupled to said second coupling and a second end portion secured to said second end portion of said second tissue piercing member, said surgical clip comprising an elongated member, a pair of coils surrounding at least a portion of said elongated member, said pair of coils being serially arranged and spaced from one another along said elongated member, said elongated member being shape memory material and having an unbiased shape, which includes a plurality of loops, and a biased shape, said elongated member tending to move toward said unbiased shape from said biased shape.

The Office Action advanced that Chervitz et al. discloses the claimed invention with the exception of having self-closing clips and concluded that it would have been obvious to incorporate self-closing clips into the expandable body suture of Chervitz et al. because self-closing clips are disclosed in Wallace et al. The Office Action further advanced that the modification would serve the purpose of enhanced attachment of tissues.

A rejection based on obviousness requires there to be motivation to carry out the proposed modification. Specifically, the references relied on must provide a reason or incentive to carry out the modification and there must be some reasonable expectation of success. Both of these elements are missing.

Chervitz et al. discloses an expandable body suture where a suture is formed over at least one pledget device during manufacture. The pledget device can be formed from cloth, fabric or resinous material. A needle or needles are secured to the suture body end or ends for forming a

hole in bone, ligament or tendon and pulling the suture body therethrough to position the pledget therein. The pledget snugly fits in the hole and restricts suture body movement (col. 3, lines 2-5).

There is no reason or incentive founded in the cited references to incorporate the occlusive coils of Wallace et al. into the suture of Chervitz et al., let alone incorporating a self-closing clip into the suture. Further, the references are devoid of any suggestion as to how the proposed modification would be carried out to achieve any desired result. Therefore, there is no motivation to combine the references as set forth in the rejection. The rejection appears to be based on an “obvious to try” standard when the Federal Circuit has categorically rejected such a standard as nothing more than impermissible hindsight.

Regarding the Examiner’s argument that the proposed modifications will enhance tissue attachment, there is no support for this in the cited references. The deficiencies in the cited references cannot be remedied by general conclusions about what one believes would be basic knowledge of one of ordinary skill in the art. Rather, there must be some concrete evidence in the record to support a position of obviousness. If the Examiner is relying on personal knowledge, Applicant respectfully requests an affidavit that provides citations for support.

Since there is no reason to provide the suture of Chervitz et al. with coils or clips as set forth in Applicant’s claims 15-19, 24-26, and 36-38, withdrawal of the rejection under Section 103 is requested.

Applicant further submits that Chervitz et al does not disclose or suggest tissue piercing members that are releasably coupled to the device of Chervitz et al. as set forth in Applicant’s claims 15 and 24. Chervitz et al. discloses that needles 12 are permanently secured to suture body 11 (see Col. 2, lines 44-47 where it states that the needles are connected to the suture body by swaging, adhesive or the like). In contrast, Applicant’s claimed apparatus has tissue piercing members releasably coupled to a fastener and needs does not require cutting or breaking to remove the piercing members.

If the needles in Chervitz et al. were releasably attached or coupled to the suture, they would not need to be “cut” or “broken” to disconnect them from the device; the coupling simply could be released. To interpret the “releasably” attached or “releasably” coupled claim language otherwise would be tantamount to saying that two pieces of steel that are welded together are “releasably” coupled to one another because the weldment could be cut with cutting tools.

Certainly, this argument is not reasonable. To interpret “releasably coupled” to be the same thing as “coupled” is improper because it gives no weight or meaning to the term “releasably.”

Further to the forgoing, neither of the references disclose or suggest the elongated member being shape memory material and having an unbiased shape, which includes a plurality of loops as described above regarding independent claim 31 and as set forth in Applicant’s independent claim 36 from which claims 37 and 38 depend.

The remaining claims, which depend from independent claims 24 and 36 are allowable for reasons provided above as well as for containing subject matter not disclosed or suggested in the cited references. For example, the cited references do not disclose or suggest the release mechanism described in Applicant’s claims 16, 17, 25 and 26, or the couplings described in claims 18, 19, 37 and 38.

If the Examiner maintains any of the foregoing rejections, Applicant requests that the Examiner clearly point to specific examples in the cited references that support any rejection so maintained.

New claims 39-55 also are not disclosed or suggested in the cited references.

Applicant submits that the pending claims are now in condition for allowance and respectfully requests the issuance of a formal Notice of Allowance at an early date. If a telephone interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the number provided below.

In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due, including additional claims fees, in connection with

the filing of this document to Deposit Account No. 13-2546 referencing Attorney Docket No. P-21814.00.

Respectfully submitted,

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